UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,443	07/02/2003	Andrew Lawrence Darrow	ORT-1644CIP	8116

27777 7590 07/14/2005

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,443	DARROW ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *8-21* is/are withdrawn from consideration.

5)☒ Claim(s) *4-7* is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *1-3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election, without traverse, of Invention I, Claims 1-7, in the response of June 9, 2005 is acknowledged. Claims 1-21 are pending. Claims 8-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-7 are hereby examined.

Examiner's note: The current claim set, filed July 2, 2003, has two claims numbered 18. Therefore, the second claim numbered 18 and Claims 19 and 20 are herein renumbered as Claims 19-21. It is suggested that, in response to this action, Applicants submit a new, corrected claim listing.

Specification-Objections

The first sentence of the specification should be updated to state that US application 10/189, 099 was abandoned on July 9, 2004.

Abstract

The Abstract is objected to for poor grammar.

Claims-Objections

Claim 1 is objected to for having a space before the period.

Claims 2 and 3 are objected to for poor grammar as follows.

For Claim 2, "12 sequential nucleotides from nucleotides 1 to 1038" would be more clearly stated as "12 sequential nucleotides of residues 1 to 1038".

For Claim 3, "identity to SEQ ID NO: 1 from nucleotide 1 to 1038 of SEQ ID NO: 1" would be more clearly stated as "identity to nucleotides 1 to 1038 of SEQ ID NO: 1".

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

In this regard, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid molecule of SEQ ID NO: 1 and the encoded polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for any nucleic acid molecule comprising a nucleotide sequence having at least 90% identity to a nucleic acid fragment encoding residue 1-9 of SEQ ID NO: 2, or any nucleic acid molecule comprising at least 12 contiguous nucleotides of residues 1-1038 of SEQ ID NO: 1, or any nucleic acid molecule having at least 70% identity with residues 1-1038 of SEQ ID NO: 1. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 is so broad as to encompass any nucleic acid molecule comprising a nucleotide sequence having at least 90% identity to a nucleic acid fragment encoding residue 1-9 of SEQ ID NO: 2. Claim 2 is so broad as to encompass any nucleic acid molecule comprising at least 12 contiguous nucleotides of residues 1-1038 of SEQ ID NO: 1. Claim 3 is so broad as to encompass any nucleic acid molecule having at least 70% identity with residues 1-1038 of SEQ ID NO: 1. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 2 and the nucleotide sequence of SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Wishart et al, 1995;

Witkowski et al, 1999). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claim 1, which encompasses all nucleic acid molecules comprising a nucleotide sequence having at least 90% identity to a nucleic acid fragment encoding residue 1-9 of SEQ ID NO: 2. The specification does not support the broad scope of Claim 2, which encompasses all nucleic acid molecules comprising at least 12 contiguous nucleotides of residues 1-1038 of SEQ ID NO: 1. The specification does not support the broad scope of Claim 3, which encompasses all nucleic acid molecules having at least 70% identity with residues 1-1038 of SEQ ID NO: 1. The specification does not support the broad scope of Claims 1-3 because the specification does not establish: (A) the function of all polypeptides encoded by the recited polynucleotides; (B) regions of the protein structure which may be modified without effecting the desired activity; (C) the general tolerance of the desired activity to modification and extent of such tolerance; (D) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of nucleic acid molecules with an enormous number of modifications of the polynucleotide of SEQ ID NO: 1, wherein the nucleic acid molecule encodes a protein with any function. The scope of the claims must bear a reasonable correlation

with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of nucleic acid molecules (i) comprising a nucleotide sequence having at least 90% identity to a nucleic acid fragment encoding residue 1-9 of SEQ ID NO: 2, (ii) comprising at least 12 contiguous nucleotides of residues 1-1038 of SEQ ID NO: 1, or (iii) having at least 70% identity with residues 1-1038 of SEQ ID NO: 1.

The specification does not contain any disclosure of the structure or function of all said nucleic acid molecules. The genus of polynucleotides that comprise these above nucleic acid molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses the structure and function of only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and

exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jalkanen et al, 1998. Jalkanen et al teach a polynucleotide having 96.3% identity to a nucleic acid encoding residues 1-9 of SEQ ID NO: 2. Therefore, Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jalkanen et al, 1998.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg et al, 2001. Strausberg et al teach a polynucleotide comprising 23 contiguous residues of amino acids 1-1038 of SEQ ID NO: 1. Therefore, Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg et al, 2001.

Allowable Subject Matter

Claims 4-7 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

AU 1652